K033881

MAR - 2 2004

510(k) Summary

OFFICIAL CONTACT:	Troy A. Jack Regulatory Affairs Analyst Medrad, Inc. One Medrad Drive Indianola, PA 15051 (412) 767-2400 ext. 3305
CLASSIFICATION NAME:	Injector with Syringe, Angiographic
COMMON NAME(S):	Powered Injector with Syringe
PROPRIETARY NAME:	Medrad Stellant CT Injector System with Imaging System Interface Module
PREDICATE DEVICE:	Medrad Stellant CT Injector System (K023183)
INTENDED USE:	The Medrad Stellant CT Injector System is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications. The ISI module option is intended for the specific purpose of allowing an injector to interface with a CT scanner.

DEVICE DESCRIPTION AND COMPARISON TO UNMODIFIED PREDICATE:

The Medrad Stellant CT Injector System with the ISI feature maintains the same intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate device. The Stellant CT Injector System with ISI Module is a syringe-based fluid delivery system indicated for delivery of contrast media during computed tomography procedures. It is intended to be used for the specific purpose of injecting intravenous contrast medium into the human vascular system for computed tomography studies. The addition of the ISI Module option to the Stellant CT Injector System simply establishes an interface between the injector and the CT scanner.

The Stellant CT Injector System with ISI Module is comprised of the same main components as the predicate device: an Injector Head, a Display Control Unit (DCU) and sterile disposables. The Imaging System Interface Module is added to the system as an accessory. Differences between the predicate device and the Stellant CT Injector System with ISI functionality are detailed in the following Comparison Matrix:

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TABLE 1 – COMPARISON OF STELLANT INJECTOR SYSTEM with ISI MODULE AND STELLANT CT INJECTOR SYSTEM

Feature	Predicate Device: Stellant CT Injector System (K023183)	Proposed Device: Stellant CT Injector System with ISI Module
Intended Use	Intended to be used for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications. The ISI module option is intended for the specific purpose of allowing an injector to interface with a CT scanner.	Same
Single or Dual Syringe System	Single and dual syringe models	Same
Information Display	Color LCD	Same
Programming Keys	Non-dedicated keys – software determined	Same
Touch screen	Yes	Yes
Multi-Phase	1 – 6 phases per injection	Same
Arming Modes	Single	Same
Protocol Storage Capability	32 protocols	Same
Hold Capability	20 minutes max.	Same
Scan Delay	1 – 300 seconds	Same
Safety Stop Mechanism	Multi-layered software stops with backup monitoring	Same
Syringe System	Single syringe model: 200 ml syringe Dual syringe model: two 200 ml syringes	Same
Programmed Volume	1 to 200 ml	Same
Volume Remaining Readout	LED on injector head; graphical and numeric on LCD	Same
Fill Rate	Variable up to 10 ml/sec	Same
Flow Rate	0.1ml/s to 10.0 ml/s	Same
Programmable Pressure Limit	325 PSI default, user settable 50 to 300 PSI	Same
Pause	Programmable – 1 sec to 900 sec in 1 sec increments	Same
Autofill	Fill rate 4 ml/sec	Same
Retract Control	Yes (Automatic)	Yes
Remote Start Switch	Yes	Yes
Pressure Graph	Yes	Yes
Syringe Sensing	Yes	Yes
Autoload	Yes	Yes
Auto Dock/Retract/Advance	Yes; user-selectable autodock and advance; user-selectable auto-retract	Yes. Same functionality.
Protocol Lock / Remote Arming	Yes	Yes
Remote Check for Air (from Head)	Yes	Yes
Scan Delay	1sec to 300 sec in 1sec increments	Same
Store/Recall	32 protocols	Same
Test Inject	Yes	Yes
Syringe Heat Maintainer	Yes	Yes
Flow Profile Display	Yes	Yes

TABLE 2 COMPARISON OF STERILE DISPOSABLES

Packaging	Tyvek lid covering polystyrene tray	Same
Sterilization	EtO sterilization	Same
Method of determining Pyrogen-Freeness	Limulus Amebocyte Lysate test to USP requirements	Same
Luer Fittings	ISO 594-1 & ISO 594-2 compliant design	Same
Syringe:		
Barrel Material Composition	Voridian (Eastman) 7352 PET	Same
Barrel Length	7.504"	Same
Barrel OD	2.002"	Same
Barrel ID	1.844"	Same
Plunger Material Composition	GE Lexan 141 Polycarbonate	Same
Plunger Cover	Helvoet Pharma Polyisoprene R2522-58	Same
Plunger Silicone Coating	Dow Corning 360	Same
Barrel Flange	Easy-engage design for non-rotational orientation (no alignment necessary)	Same
Syringe sensing feature	Grooves at bottom of barrel to be optically identified	Same
Connector Tubing Components:		
Maximum Pressure	400	Same
Tube Material	Unichem PVC	Same
Tube Length	60"	Same
Bonding Agent	Cyclohexanone	Same
T-connector	Medical grade polycarbonate	Same
Burron DP 1000 Spike	ABS	Same
Priming Tube	Low density polyethylene	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2004

Medrad, Inc.
c/o Mr. Troy A. Jack
Regulatory Affairs Analyst
One Medrad Drive
Indianola, Pa 15051

Re: K033881
Medrad Stellant CT Injector System with Imaging System Interface Module
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II (two)
Product Code: DXT
Dated: December 12, 2003
Received: December 15, 2003

Dear Mr. Jack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033881

Device Name: Medrad Stellant CT Injector System with Imaging System Interface Module

Indications For Use:

The Medrad Stellant CT Injector System is intended for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications. The ISI module option is intended for the specific purpose of allowing an injector to interface with a CT scanner.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033881